UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/598,042	06/20/00	TANG Y	784CIP2

HM22/0913

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EXAMINER	
ZHOU, S	
ART UNIT	**PAPER NUMBER**
1631	9

DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/598,042	Applicant(s) TANG ET AL.	
	Examiner Shubo "Joe" Zhou	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-9,12-19 and 23-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Amendments

Applicants' election of Group II (10-11, and 20-21) and SEQ ID NO:2, in Paper No.8, filed 8/9/01, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 1-28 are currently pending, claims 10-11, and 20-21 are under examination, and claims 1-9, 12-19, and 23-28 are withdrawn from further consideration as being drawn to non-elected inventions.

Specification

The specification is objected to because of the following:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Appropriate correction is required.

Priority

It is brought to applicants' attention that for the purpose of examination, priority has not been granted to the claimed applications, 09/552,317 and 09/488,725 for the elected invention because the Office has not been able to determine that the elected invention was disclosed in the claimed applications due to the defective CRFs of the Sequence Listings in the applications. Prior arts published after the claimed

applications but before the filing date of the instant application may have been cited in this Office action. The applicants are requested to provide evidence that the elected inventions are disclosed in the claimed application if they wish to contest the citation of the intervening prior arts.

Claim Rejections-35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, Written Description Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

See also the MPEP at §§ 2107 - 2107.02.

Claims 10-11, and 20-21 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Claims 10-11, and 20-21 are drawn to polypeptide encoded by polynucleotides. The claimed polypeptide is not supported by a specific asserted utility because the disclosed uses of the polypeptide are not specific and are generally applicable to any polypeptide. For example, the specification states that the polypeptides can be used in research, etc. (see page 37). All these possible uses are generic to any polypeptides encoded by a nucleic acid sequence. As a matter of fact, the specification summarizes pretty much of the modern biotechnology in general, but fails to connect the specifically elected sequence to any particular or specific utility. This wishlist-like desire for a utility for the claimed sequence falls short of a readily available utility.

Further, the claimed nucleic acid is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example,

the specification states that the polypeptide can be utilized in gene therapy, etc. (page 33). However, this utility depends on the activity/function of the polypeptide which is yet to be discovered by further research. The apparent need for such research clearly indicates that the polypeptide is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving the claimed nucleic acid have asserted or identified specific and substantial utilities. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context for use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds.

Please note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed.

Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well established for the elected protein compound.

Claims 10-11, and 20-21 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-

established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 10-11, and 20-21 are rejected, as discussed below, also under 35 U.S.C. 112, first paragraph, as containing subject matter which lacks written description in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 10-11, and 20-21 are drawn to a genus of polypeptides: polypeptides encoded by nucleic acids comprising the nucleotide sequence of SEQ ID NO:2 , polypeptides encoded by sequences hybridizing to the sequence of SEQ ID NO:2, and the protein variants of the above polypeptides. The instant specification, however, only discloses species, i.e. the polypeptide encoded by the DNA sequence of the elected SEQ ID NO. However, given the broad scope of the claims, they are drawn to any polypeptides encoded by polynucleotide or nucleic acid that minimally contains the sequence of the claimed SEQ ID NO, including any full length gene which contain the sequence, any fusion constructs, any RNAs or cDNAs, etc. There is substantial variability among the species of polynucleotides or nucleic acids encompassed within the scope of the claims and there is substantial variability among the polypeptides encoded by these polynucleotides because the claimed SEQ ID NO is only a fragment of any full-length gene or cDNA species, or any vector due to the use of the open language "comprising". Since the claimed genus encompasses species yet to be discovered, DNA constructs that encode fusion proteins, protein variants, etc., the mere disclosure of a species: polypeptide sequence encoded by the polynucleotide sequence

of the claimed SEQ ID NO, does not provide an adequate description of the claimed genus. In view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs or RNAs encompassed in claims 10-11, and 20-21, which comprise the sequence of the claimed SEQ ID NO encoding the claimed polypeptides.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the polypeptide sequence encoded by SEQ ID NO:2, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides/proteins encoded by the polynucleotide/nucleic acid claimed, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to

> recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only the polypeptide sequence encoded by SEQ ID NO:2, but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112, first paragraph. The species specifically disclosed is not representative of the genus because the genus is highly variant.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (See page 1115).

In summary, claims 10-11, and 20-21 contain subject matter which lacks written description in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

For reasons stated above, claims 10-11, and 20-21 are rejected under 35 U.S.C. 112, first paragraph, also because the specification, while being enabling for the polypeptide encoded by the elected SEQ ID NO:2, in claims 10-11, and 20-21, does not reasonably provide enablement for the full breadth of the claims. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 10-11, and 20-21 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-11 are indefinite because they are dependent from non-elected claim 1.

Claims 20-21 are indefinite because they claim polypeptides listed in the sequence listing. There is no guarantee that the Sequence Listing remains unchanged. Further, claim 20 is written as including an apparent Markush group. However, it is an improper Markush claim and therefore the metes and bounds of the claim is not clear

due to the use of the phrase "selected from the group consisting...or..." It is unclear what else could be selected as a nucleic acid sample in addition to those that are recited. The proper form of a Markush group should recite members as being "selected from the group consisting of...and ..." See MPEP 2173.05(h).

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> **(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

Claims 10-11, and 20 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Rowen et al. (GenBank Acc. No. AF110520, 12/23/1998).

Rowen et al. disclose a nucleotide sequence encoding a polypeptide and the sequence is a complement of, and hybridizes to the nucleotide sequence of the instant SEQ ID NO;2, and the protein encoded by the database sequence is a variant of the polypeptide encoded by the instant SEQ ID NO:2, as required in claims 10-11 (see alignment enclosed). Furthermore, the polypeptide encoded by the database sequence comprises an amino acid of the polypeptide encoded by the instant SEQ ID NO:2, as required in claim 20. It should be pointed out that any sequence with any percentage of complementarity to the sequence of SEQ ID NO:2 is interpreted as a complement of the sequence of SEQ ID NO:2 absent a clear definition in the specification.

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rowen et al. (GenBank Acc. No. AF110520, 12/23/1998) in view of Chin et al. (US patent: 6,197,599, issued March 6, 2001, filed July 30, 1998).

As set forth above, Rowen et al. disclose a nucleotide sequence encoding a protein comprising an amino acid of the protein encoded by the instant SEQ ID NO:2. Chin et al. teach of making and using a protein array (page).

Thus, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine the teachings and/or motivations of Rowen et al. and Chin et al. to make and use the claimed invention.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is 703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

ARDIN H. MARSCHEL
PRIMARY EXAMINER

S. "Joe" Zhou, Ph.D.

Patent Examiner